



# Caffeine, Calories, and Coordination: Jurisdictional Developments in Federal Alcohol Regulation

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Caffeine, Calories, and Coordination:  
Jurisdictional Developments in Federal Alcohol Regulation

Rebecca C. Ellis

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## *Abstract*

*Even though alcoholic beverages fall under the definition of “food” in the Federal Food, Drug & Cosmetic Act, the Food and Drug Administration (FDA) does not regulate such beverages’ ingredient and nutrition labeling as it does for other foods. Instead, jurisdiction over alcoholic beverage labeling falls to the Alcohol and Tobacco Tax and Trade Bureau (TTB), a division of the Department of Treasury. The present system of divided jurisdiction is the product of a series of historically contingent events and inter-agency conflicts, and it has caused confusion and friction in this regulatory area for four decades and counting.*

*This paper explores some of the current issues in alcoholic beverage labeling jurisdiction. It begins by reviewing the history of such jurisdiction, how TTB came to have exclusive control over alcoholic beverage labeling, and the failed attempts to reform the system. It then examines two recent events that have called for cooperation between FDA and TTB: the public outcry over the health hazards of caffeinated alcoholic beverages, and the Patient Protection & Affordable Care Act’s requirement for calorie labeling on restaurant menus. In the former case, the two agencies were able to work together to take concerted action, yet in the latter case they found themselves at odds. This paper examines the differences between the two situations and analyzes some administrative strategies that might be able to encourage more successful cooperation and reduce the risks of regulatory arbitrage.*

## INTRODUCTION

Section 201(f)(1) of the Federal Food, Drug & Cosmetic Act<sup>1</sup> (FDCA) defines “food” as “articles used for food or drink for man or other animals,”<sup>2</sup> and Sections 301 and 403 together grant authority to the agency now known as the Food and Drug Administration (FDA) to regulate the labeling of food products in interstate commerce.<sup>3</sup> Pursuant to this authority, FDA has issued labeling requirements for most beverages that Americans consume on a daily basis, and we have become accustomed to seeing the familiar ingredients list and “Nutrition Facts” box on our cans of soda, cartons of juice, and even bottles of water. But one glaring exception remains: this information does not appear on our alcoholic beverages. Due to a confluence of historical factors, the regulatory authority for setting labeling requirements on most alcoholic drinks<sup>4</sup> sits not with FDA but with the Alcohol and Tobacco Tax and Trade Bureau (TTB), an agency within the Department of Treasury.<sup>5</sup>

TTB’s jurisdiction over alcoholic beverage labeling has been controversial over the years, and it remains so now. FDA and TTB have wrangled both in the courts and behind the administrative scenes over which agency will provide which types of oversight over which areas of the alcohol industry. The statutory mandates are less than elucidating, making the battle one that turns more on political expedience and industry influence than on legal theories of interpretation. While the agencies have operated under the terms of a regulatory détente for over twenty years, proposals for reform have turned up in the pages of the Congressional Record and the Federal Register no less than five times since 1993. And recent controversies involving alcoholic bever-

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<sup>1</sup> Ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C.).

<sup>2</sup> *Id.* § 201(f)(1), 52 Stat. at 1040 (codified at 21 U.S.C. § 321(f)(1)).

<sup>3</sup> *Id.* §§ 301, 403, 52 Stat. at 1042, 1047 (codified as amended at 21 U.S.C. §§ 331, 343).

<sup>4</sup> *See infra* note 62.

<sup>5</sup> *See About TTB*, TTBGov, <http://www.ttb.gov/about/history.shtml> (last visited Apr. 17, 2012).

ages have renewed the question whether FDA and TTB can effectively share jurisdiction without risking harm to consumers or succumbing to regulatory arbitrage by the alcohol industry.

This paper will examine these recent events in light of the regulatory history and assess how (or whether) the current jurisdictional structure is capable of providing meaningful solutions to these significant developing issues. Part I will review the development of TTB jurisdiction over alcoholic beverage labeling, starting at the beginning of modern federal alcohol regulation in the post-Prohibition era and extending to the most recent congressional and administrative efforts at making the system more rational. Part II will describe the recent controversy over caffeinated alcoholic beverages — epitomized by the well-publicized outcry over “Four Loko,”<sup>6</sup> a combination energy drink and malt beverage designed to appeal to underage drinkers — and assess the coordinated efforts of FDA and TTB to respond to consumer concerns. This episode provides a useful illustration of a nearly best-case scenario for joint regulatory action. Part III will then address the developing jurisdictional conflict surrounding the provision of the Patient Protection and Affordable Care Act<sup>7</sup> that requires FDA to promulgate rules under which chain restaurants must display calorie counts for each item on their menus.<sup>8</sup> FDA’s inability to include alcoholic beverages in these requirements has created a stumbling block to full implementation of the purposes of the provision and has created an opportunity for arbitrage by the alcohol industry. This issue thus serves as a counterpoint to the caffeinated beverages incident by demonstrating the very real shortcomings of divided jurisdiction. Part IV concludes.

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<sup>6</sup> See *Products*, FOUR LOKO, <http://www.drinkfour.com/products> (last visited Apr. 17, 2012).

<sup>7</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of the U.S. Code). Certain parts of this statute are, of course, pending constitutional review in the U.S. Supreme Court at the time of this writing. However, the Court’s ruling on the health insurance aspect of the law is unlikely to affect the provision discussed in this paper.

<sup>8</sup> See *id.* § 4205, 124 Stat. at 573-76 (codified at 21 U.S.C. § 343(q)(5)(A)).

I. JURISDICTIONAL CONFLICTS OVER ALCOHOL LABELING REGULATIONS:  
PAST AND PRESENT

*A. The Early Years: From the 21st Amendment to the 1970s*

Upon the repeal of Prohibition in December 1933,<sup>9</sup> President Franklin D. Roosevelt issued an executive order instituting the first federal body for the regulation of alcoholic beverages: the Federal Alcohol Control Administration (FACA).<sup>10</sup> President Roosevelt gave FACA authority to regulate “false and misleading labeling” of alcoholic beverages; the definition of such false labeling was explicitly borrowed from the Pure Food and Drugs Act in force at the time.<sup>11</sup> However, the Supreme Court soon invalidated the statute that had given President Roosevelt the authority to create FACA.<sup>12</sup> Congress responded by passing the Federal Alcohol Administration Act<sup>13</sup> (“1935 Act”), which created the Federal Alcohol Administration (FAA) within the Department of Treasury.<sup>14</sup> In addition to conferring broad taxing and permitting powers,<sup>15</sup> the 1935 Act also transferred to FAA the labeling regulation authority previously held by FACA,<sup>16</sup> which included the ability to prohibit misleading statements “irrespective of falsity”<sup>17</sup> and to require labels that would “provide the consumer with adequate information as to the identity and quality of the products.”<sup>18</sup> Alcohol producers would have to get pre-approval of their labels from FAA before introducing their products into interstate commerce.<sup>19</sup> Notably, however, the elements

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<sup>9</sup> See U.S. CONST. amend. XXI.

<sup>10</sup> See Iver P. Cooper, *The FDA, the BATF, and Liquor Labeling: A Case Study of Interagency Jurisdictional Conflict*, 34 FOOD DRUG COSM. L.J. 370, 371 (1979).

<sup>11</sup> *Id.* at 371-72.

<sup>12</sup> *Id.* at 372; see *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935) (invalidating National Industrial Recovery Act as an unconstitutional delegation of legislative power).

<sup>13</sup> Ch. 814, 49 Stat. 977 (1935) (codified as amended at 27 U.S.C.).

<sup>14</sup> *Id.* § 2(a), 49 Stat. at 977 (repealed 1936).

<sup>15</sup> See *id.* §§ 3-4, 11-16, 49 Stat. at 978-81, 987-89.

<sup>16</sup> See *id.* § 5(e), 49 Stat. at 982-84.

<sup>17</sup> *Id.* § 5(e)(1).

<sup>18</sup> *Id.* § 5(e)(2).

<sup>19</sup> Cooper, *supra* note 10, at 373.

required to appear on these labels were alcohol content, quantity of product, manufacturer, and compliance with standards of identity<sup>20</sup> — not a list of ingredients.<sup>21</sup>

In 1940, Congress abolished FAA and transferred all of its functions under the 1935 Act to the Alcohol Tax Unit of the Bureau of Internal Revenue<sup>22</sup> (now the IRS). Those functions were transferred again in 1972 to the Bureau of Alcohol, Tobacco and Firearms (ATF), another agency within the Department of Treasury.<sup>23</sup> Following a major reorganization of ATF under the Homeland Security Act of 2002,<sup>24</sup> responsibility for administering the 1935 Act fell to the newly created TTB, which remained in Treasury while other functions of ATF were transferred to the Department of Justice.<sup>25</sup>

Congress passed the FDCA three years after the 1935 Act, but the terms of the FDCA contained no specific references to whether the scope of FDA’s new labeling power included alcoholic beverages.<sup>26</sup> Yet the FDCA’s definition of “food,” by its plain meaning, appears to encompass such beverages as “articles used for . . . drink for man.”<sup>27</sup> Elaine Byszewski, examining the legislative histories of both the Pure Food and Drugs Act of 1906<sup>28</sup> and the FDCA, has

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<sup>20</sup> Federal Alcohol Administration Act, § 5(e)(2), 49 Stat. at 982.

<sup>21</sup> At the time the 1935 Act was passed, its labeling requirements were in fact the most stringent affirmative labeling obligations placed on any producers of consumable products. See Mary Hancock, *Federal Jurisdictional Disputes in the Labeling and Advertising of Malt Beverages*, 34 FOOD DRUG COSM. L.J. 271, 273-74 (1979) (citing Wallace A. Russell, *Controls Over Labeling and Advertising of Alcoholic Beverages*, 7 LAW & CONTEMP. PROBS. 645, 649 (1940)). As discussed *infra*, however, the advent of FDA ingredient labeling requirements under the FDCA would change this situation.

<sup>22</sup> Cooper, *supra* note 10, at 372.

<sup>23</sup> *Id.*

<sup>24</sup> Pub. L. No. 107-296, 116 Stat. 2135 (codified as amended in scattered sections of the U.S. Code).

<sup>25</sup> *Id.* § 1111, 116 Stat. at 2274; see also *About TTB*, *supra* note 5.

<sup>26</sup> The word “alcohol” only appeared in the FDCA with reference to adulterated confections, see FDCA § 402(d), 52 Stat. at 1047, and to misbranded drugs, see *id.* § 502(e)(2), 52 Stat. at 1051.

<sup>27</sup> 21 U.S.C. § 321(f)(1).

<sup>28</sup> Ch. 3915, 34 Stat. 768 (superseded by FDCA, 1938).

demonstrated that the Congress that enacted the former law specifically intended for alcoholic beverages to fall under the statute's purview<sup>29</sup> and that the Congress of the latter did not intend to change the earlier understanding of the scope of "food" subject to FDA's control.<sup>30</sup> Yet for over three decades following passage of the FDCA, FDA took the position that it would defer to FAA's (and successor agencies') regulations of alcoholic beverage labeling, even though alcoholic beverages were within the coverage of the FDCA's labeling authority.<sup>31</sup> The alcohol agencies thus assumed primary control over alcoholic beverage labeling, although they likewise seemed to recognize concurrent jurisdiction, as when the Alcohol Tax Unit informed regulated parties in 1962 that its label approvals did not confer any exemption from FDA rules.<sup>32</sup> FDA alone, however, had regulatory jurisdiction over adulteration of alcoholic beverages during this period.<sup>33</sup>

*B. Interagency Breakdowns in the 1970s and the  
Creation of the Modern Regime*

The modern battle over ingredient labeling for alcoholic beverages began in 1972, when the Center for Science in the Public Interest (CSPI), a consumer advocacy organization, began lobbying both FDA and ATF for rulemaking on such labeling.<sup>34</sup> FDA, pursuant to its longstanding policy, initially deferred to ATF.<sup>35</sup> ATF did begin to explore this option, and in August 1974, it published its first Notice of Proposed Rulemaking on alcoholic beverage ingredient la-

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<sup>29</sup> See Elaine Byszewski, *What's in the Wine? A History of FDA's Role*, 57 FOOD & DRUG L.J. 545, 547-50 (2002).

<sup>30</sup> See *id.* at 555-60.

<sup>31</sup> Cooper, *supra* note 10, at 373.

<sup>32</sup> *Id.* at 373-74.

<sup>33</sup> Byszewski, *supra* note 29, at 561.

<sup>34</sup> Cooper, *supra* note 10, at 375. As with so many issues in food and drug regulation, the impetus came from well-publicized incidents of adverse health effects occurring or threatening to occur — here, as a result of substances that had been added to beer. See Hancock, *supra* note 21, at 277-78 (describing incidents of cobalt poisoning in the mid-1960s and the discovery in 1971 that a common beer and wine preservative could break down into a cancer-causing substance).

<sup>35</sup> Cooper, *supra* note 10, at 375.



beling.<sup>36</sup> The agency stated in its explanation of the proposed rule: “[T]oday’s consumers want to know, and, we feel, have a right to know, what ingredients have been used in the production of the alcoholic beverages they buy.”<sup>37</sup> Shortly thereafter, FDA and ATF entered into a Memorandum of Understanding (MOU) in which FDA once again asserted its statutory authority to regulate alcohol labeling but also recognized the agencies’ ongoing efforts to cooperate on developing “comprehensive ingredient labeling regulations” for alcoholic beverages that would comply with both agencies’ statutory mandates.<sup>38</sup> The MOU stated that ATF would be the “primary agency” for promulgating and enforcing such labeling regulations but that those regulations would be “consistent” with the FDCA’s food labeling requirements.<sup>39</sup>

This comity did not last long, however. FDA soon became dissatisfied with some of ATF’s proposals for the new regulations,<sup>40</sup> and over a year after its initial Notice, ATF announced that it would not promulgate a final rule, on the basis that ingredient labeling would be too costly, would provide little benefit to consumers, and would hinder international trade negotiations.<sup>41</sup> FDA promptly announced that it was abrogating the MOU and that it would take action to enforce its own ingredient labeling requirements on producers of alcoholic beverages.<sup>42</sup> This interagency conflict stemmed in part from the two agencies’ different ultimate responsibili-

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<sup>36</sup> See Malt Beverages Labeling and Advertising, 39 Fed. Reg. 27,812 (Aug. 1, 1974). While this first Notice focused specifically on malt beverages, ATF later issued similar Notices of Proposed Rulemaking for wine, see Wine Labeling and Advertising, 40 Fed. Reg. 6349 (Feb. 11, 1975), and distilled spirits, see Distilled Spirits Labeling and Advertising, 40 Fed. Reg. 6354 (Feb. 11, 1975).

<sup>37</sup> Malt Beverages Labeling and Advertising, 39 Fed. Reg. at 27,812.

<sup>38</sup> See Labeling Regulations Promulgated Under the Federal Alcohol Administration Act: Memorandum of Understanding with the Bureau of Alcohol, Tobacco and Firearms, 39 Fed. Reg. 36,127 (Oct. 8, 1974).

<sup>39</sup> *Id.* at 36,128.

<sup>40</sup> See Cooper, *supra* note 10, at 375 & n.38.

<sup>41</sup> See Ingredient Labeling of Malt Beverages, Distilled Spirits and Wine: Withdrawal of Notices of Proposed Rulemaking, 40 Fed. Reg. 52,613 (Nov. 11, 1975).

<sup>42</sup> See Alcoholic Beverages Labeling, 40 Fed. Reg. 54,455 (Nov. 24, 1975).

ties: FDA saw its purpose as protecting consumers, which it usually did by making sure that products under the heading of “food” had ingredient labels, whereas ATF, as a Treasury agency, was less consumer-oriented and was sensitive to its mission of working with industry to ensure the collection of taxes.<sup>43</sup>

In 1976, the two agencies attempted to resolve their standoff and agree on another MOU, but their efforts would be short-circuited by the courts.<sup>44</sup> A group of distillers, winemakers, and alcohol industry trade associations brought suit to enjoin FDA from enforcing its labeling regulations against alcoholic beverage producers.<sup>45</sup> In *Brown-Forman Distillers Corp. v. Mathews*, the district court examined the statutory texts and legislative histories of both the FDCA and the 1935 Act,<sup>46</sup> and it concluded that Congress had intended to give ATF exclusive jurisdiction over alcoholic beverage labeling regulations.<sup>47</sup> A finding of concurrent jurisdiction, the court concluded, would subject alcohol producers to “duplication and inconsistent standards” due to the different requirements of the two statutes’ labeling provisions.<sup>48</sup> When confronted with the ques-

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<sup>43</sup> See Cooper, *supra* note 10, at 383, 389. Compare DEP’T OF HEALTH & HUMAN SVCS., FOOD & DRUG ADMIN., FISCAL YEAR 2013 JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEE 3 (2012), available at <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM291555.pdf> (describing FDA’s mission as “responsib[ility] for protecting the public health by assuring the safety, efficacy and security of . . . our nation’s food supply”), with ALCOHOL & TOBACCO TAX & TRADE BUREAU, FISCAL YEAR 2013 PRESIDENT’S BUDGET SUBMISSION 3 (2012), available at <http://www.ttb.gov/pdf/budget/2013cj.pdf> (describing TTB’s mission as “[t]o collect the federal excise taxes on alcohol, tobacco, firearms, and ammunition, and assure compliance with federal tobacco permitting and alcohol permitting, labeling, and marketing requirements to protect consumers”).

<sup>44</sup> See Cooper, *supra* note 10, at 376-77.

<sup>45</sup> See *Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5, 6 (W.D. Ky. 1976). Iver Cooper notes that the plaintiffs “chose their forum carefully,” filing suit in the district that was “the heart of the whiskey industry.” Cooper, *supra* note 10, at 377.

<sup>46</sup> See *Brown-Forman*, 435 F. Supp. at 9-12.

<sup>47</sup> *Id.* at 12. The court confirmed, however, that FDA would retain jurisdiction over incidents of adulteration in alcoholic beverages. See *id.* at 6 n.2, 12.

<sup>48</sup> *Id.* at 14 (quoting *United States v. Nat’l Ass’n of Secs. Dealers*, 422 U.S. 694, 735 (1975)) (internal quotation marks omitted); see also *id.* at 14-15 (detailing differences between FDA’s and

tion whether to appeal the district court's ruling, the Department of Justice faced conflicting pressures from FDA and ATF, and ultimately the Office of Management and Budget, under pressure from wine lobbyists, convinced Justice not to appeal.<sup>49</sup> In the wake of the rulemaking breakdown and the *Brown-Forman* decision, Congress attempted to intervene, but it could not reconcile its own internal conflicts between representatives and senators who sided with ATF and those who sided with FDA.<sup>50</sup>

ATF issued a new Notice of Proposed Rulemaking in 1979 that called for "partial" ingredient labeling requirements: producers would be permitted to list a "range" of "essential" ingredients and would be required to specifically list all "additives."<sup>51</sup> The rule did become final in 1980,<sup>52</sup> though in a watered-down form,<sup>53</sup> but it only lasted a year before ATF rescinded it,<sup>54</sup> ostensibly because it failed the new Reagan Administration's mandated cost-benefit analysis.<sup>55</sup> Angered by the rescission, CPSI re-entered the fray, filing suit to invalidate ATF's action on the basis that it was substantively prohibited by the 1935 Act and procedurally defective under the

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ATF's existing labeling regulations). *But see* Byszewski, *supra* note 29, at 565-66 (pointing out that the 1935 Act's requirement that alcohol permits be contingent on compliance with all federal laws could easily be read to include compliance with FDCA-mandated labeling regulations); Cooper, *supra* note 10, at 388 (arguing that "[t]he two sets of regulations could have been harmonized quite easily").

<sup>49</sup> See Cooper, *supra* note 10, at 377.

<sup>50</sup> See *id.* at 385.

<sup>51</sup> Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages, 44 Fed. Reg. 6740 (Feb. 2, 1979).

<sup>52</sup> Labeling and Advertising of Wine, Distilled Spirits and Malt Beverages, 45 Fed. Reg. 40,538 (June 13, 1980).

<sup>53</sup> See Byszewski, *supra* note 29, at 567 (noting that, among other compromises, the final rule allowed producers to omit ingredient lists if their labels contained an address to which consumers could write and request such a list).

<sup>54</sup> Rescission of Ingredient Labeling Regulations for Wine, Distilled Spirits and Malt Beverages, 46 Fed. Reg. 55,093 (Nov. 6, 1981).

<sup>55</sup> See Byszewski, *supra* note 29, at 567-68.

Administrative Procedure Act.<sup>56</sup> The district court ruled for the plaintiff on both theories.<sup>57</sup> But while the appeal was pending, ATF opened a new comment period<sup>58</sup> and promulgated a new rule that again rescinded the former regulations, with the exception that alcoholic beverage manufacturers still had to disclose on their labels the addition of FD&C Yellow No. 5.<sup>59</sup> The appellate court thus dismissed the appeal as moot.<sup>60</sup> CPSI filed a new suit against the updated rescission and again prevailed at the district court,<sup>61</sup> but this time the appellate court reached the merits and ruled in favor of ATF.<sup>62</sup>

Today TTB, the successor agency to ATF, retains the exclusive jurisdiction over alcoholic beverage labeling that it won in *Brown-Forman* and reinforced in the *CPSI* cases.<sup>63</sup> FDA retains concurrent jurisdiction over adulterated alcoholic beverages, but it has taken the position

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<sup>56</sup> Ctr. for Sci. in the Pub. Interest v. Dep't of the Treasury, 573 F. Supp. 1168, 1172 (D.D.C. 1983). Tellingly, the Wine Institute, an industry trade group, intervened as defendant to support the rescission. *Id.* at 1169.

<sup>57</sup> *Id.* at 1179.

<sup>58</sup> See Ingredient Labeling of Wine, Distilled Spirits and Malt Beverages, 48 Fed. Reg. 27,782 (June 17, 1983).

<sup>59</sup> Ingredient Labeling of Wine, Distilled Spirits and Malt Beverages, 48 Fed. Reg. 45,549 (Oct. 6, 1983); see Ctr. for Sci. in the Pub. Interest v. Regan, 727 F.2d 1161, 1163-64 (D.C. Cir. 1984).

<sup>60</sup> Ctr. for Sci. in the Pub. Interest, 727 F.2d at 1164, 1166.

<sup>61</sup> Ctr. for Sci. in the Pub. Interest v. Dep't of the Treasury, Civ. A. No. 84-2079, 1985 WL 9649, at \*6 (D.D.C. Oct. 30, 1985).

<sup>62</sup> Ctr. for Sci. in the Pub. Interest v. Dep't of the Treasury, 797 F.2d 995, 997 (D.C. Cir. 1986).

<sup>63</sup> See Byszewski, *supra* note 29, at 569-70. There are a few minor exceptions, however. For one, FDA has labeling jurisdiction over cooking wines as well as wines and ciders that contain less than seven percent alcohol by volume. See *id.* at 570 n.175. FDA also controls labeling for beers made from grains other than malted barley. See Marion Nestle, *Alcohol Nutritional Labeling a Regulatory Maze*, S.F. CHRON., Nov. 7, 2010, at K-4, available at <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2010/11/07/FD2D1G4OB8.DTL>. Moreover, it is worth recognizing that TTB regulations do not always preempt state laws, which can also impose certain labeling requirements. See Susan Cagann & Rick Van Duzer, *75 Years After Prohibition: The Regulatory Hangover Remains*, BUS. L. TODAY, May/June 2009, at 45, 46 (“A supplier cannot stop though [sic] at federal compliance. Thirty states require a supplier to register its labels. Federal and state laws have many content restrictions on labeling and advertising products.”). This paper, however, will focus on federal regulations.

that TTB has primary responsibility for instituting and overseeing recalls.<sup>64</sup> In 1987, FDA and ATF entered into a new MOU that confirmed each agency's sphere of authority and that obligated ATF to initiate rulemaking for labeling requirements if FDA informed it that a particular ingredient posed a public health hazard.<sup>65</sup>

### *C. Failed Attempts at Reform*

Many stakeholders, including ATF/TTB itself, have expressed dissatisfaction with the current labeling regime for alcoholic beverages in the thirty years since the *CPSI* cases, but no significant progress has yet been made. Members of Congress have twice attempted to amend the FDCA to give FDA explicit authority to require ingredient and at least minimal nutrition labeling on alcoholic beverages, once in 1993<sup>66</sup> and again in 1996.<sup>67</sup> Neither bill progressed past the House.<sup>68</sup> In 1999, a Senate bill attempted to transfer authority over alcohol warning labels to FDA<sup>69</sup> — which would have been a clear signal of congressional intent to give FDA a greater role in the alcoholic beverage area — but that bill, too, failed to advance.<sup>70</sup>

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<sup>64</sup> See Byszewski, *supra* note 29, at 570 (citing FDA Compliance Policy Guide No. 7155.04 (Nov. 1987)).

<sup>65</sup> Memorandum of Understanding, 52 Fed. Reg. 45,502 (Nov. 30, 1987) [hereinafter “1987 MOU”]; see *id.* at 45,504. The agencies had already followed this procedure in 1986, when FDA determined that undeclared sulfites posed a health hazard. See Byszewski, *supra* note 29, at 570 (citing Labeling of Sulfites in Alcoholic Beverages, 51 Fed. Reg. 34,706 (Sept. 30, 1986)).

<sup>66</sup> See Alcohol Ingredient Labeling Act of 1993, H.R. 1420, 103d Cong. (1993).

<sup>67</sup> See Alcohol Ingredient Labeling Act of 1996, H.R. 3115, 104th Cong. (1996).

<sup>68</sup> See *Bill Summary & Status 103d Congress (1993-1994): H.R. 1420 All Congressional Actions*, LIBRARY OF CONGRESS: THOMAS, <http://thomas.loc.gov/cgi-bin/bdquery/z?d103:HR01420:@@@X> (last visited Apr. 17, 2012) (reporting that last action taken on 1993 bill was referral to House Subcommittee on Health and the Environment); *Bill Summary & Status 104th Congress (1995-1996): H.R. 3115 All Congressional Actions*, LIBRARY OF CONGRESS: THOMAS, <http://thomas.loc.gov/cgi-bin/bdquery/z?d104:HR03115:@@@X> (last visited Apr. 17, 2012) (reporting that last action taken on 1996 bill was referral to House Subcommittee on Health and the Environment).

<sup>69</sup> See Alcoholic Beverage Labeling Act of 1999, S. 431, 106th Cong. (1999).

<sup>70</sup> *Bill Summary & Status 106th Congress (1999-2000): S. 431 All Congressional Actions*, LIBRARY OF CONGRESS: THOMAS, <http://thomas.loc.gov/cgi-bin/bdquery/z?d106:SN00431>:

TTB has at times attempted to institute its own changes, perhaps aware that it could face continuing congressional threats to its jurisdiction if supporters of alcoholic beverage labeling are not satisfied by its efforts. In 1993, in response to a petition, ATF published a notice seeking comment regarding a possible requirement for nutrition labeling on alcoholic beverages consistent with FDA's requirements for other foods and beverages.<sup>71</sup> After the comment period, however, ATF chose not to proceed to the process of issuing a rule.<sup>72</sup> In 2005, TTB issued a notice seeking comment on various labeling proposals, noting that the agency had received "petitions to mandate additional information, including ingredient, allergen, alcohol, calorie, and carbohydrate content" of alcoholic beverages.<sup>73</sup> TTB asked for comment on eight specific questions, including what information should be included on a prospective ingredient/nutrition label, whether such labeling should be mandatory or voluntary, and whether TTB should attempt to harmonize its requirements with FDA's.<sup>74</sup>

This time TTB did take the next step, issuing a Notice of Proposed Rulemaking in 2007 that stated TTB's intention to impose a "mandatory nutrient information panel that must include the following information: [t]he title 'Serving Facts'; serving size; the number of servings per container; the number of calories per serving; and the number, in grams per serving, of carbohydrates, fat, and protein," with an option to also include "the mandatory alcohol content statement

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@@@X (last visited Apr. 17, 2012) (reporting that last action taken was referral to Senate Committee on Commerce).

<sup>71</sup> Nutrition Labeling for Wine, Distilled Spirits, and Malt Beverages, 58 Fed. Reg. 42,517 (Aug. 10, 1993).

<sup>72</sup> See Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages, 70 Fed. Reg. 22,274, 22,278 (Apr. 29, 2005). Interestingly, both support for and opposition to the proposal was split among groups that would seem to be natural allies: for instance, CPSI and the Wine Institute both opposed it, while Seagram's and the American Association of Diabetes Educators both supported it. See *id.*

<sup>73</sup> *Id.* at 22,275.

<sup>74</sup> *Id.*

as a percentage of alcohol by volume” on that same panel.<sup>75</sup> The agency included lengthy responses to comments on each element, noting in particular that the comments it had received from consumers most often “expressed confusion as to why alcohol beverage labels do not currently bear this type of information.”<sup>76</sup> But the rule has languished in regulatory limbo ever since.<sup>77</sup> The result is that the current regulatory regime for alcoholic beverage labeling is a patchwork of disconnected instructions that TTB and its predecessors put in place over time without a unified framework such as the one presented in the 2007 proposed rule.<sup>78</sup>

## II. CAFFEINATED ALCOHOLIC BEVERAGES: THE ACHIEVEMENTS OF AGENCY COOPERATION

### A. *The Four Loko Controversy and the Cooperative Response*

Four Loko first appeared on the shelves of alcohol retailers in 2006.<sup>79</sup> With its brightly colored packaging,<sup>80</sup> low price,<sup>81</sup> high alcohol content,<sup>82</sup> and heavy infusion of caffeine,<sup>83</sup> it was

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<sup>75</sup> Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages, 72 Fed. Reg. 41,860, 41,873 (July 31, 2007).

<sup>76</sup> *Id.* at 41,866.

<sup>77</sup> See Nestle, *supra* note 63.

<sup>78</sup> See *id.* (noting the inconsistencies in current rules, such as variations in the requirement to list percentage of alcohol by volume according to the type of beverage and the percentage of alcohol in the beverage, and requiring “light” beers but not other beers to list calories on the label).

<sup>79</sup> Michelle Silva Fernandes, Note, *Party Foul: The Fourth Circuit’s Improper Application of the Commercial Speech Test in Educational Media Co. at Virginia Tech v. Swecker*, 80 FORDHAM L. REV. 1325, 1327 (2011).

<sup>80</sup> See, e.g., *Products*, FOUR LOKO, *supra* note 6.

<sup>81</sup> See Frank Bruni, *Caffeine and Alcohol: Wham! Bam! Boozled*, N.Y. TIMES, Oct. 31, 2010, at WK5, available at [http://www.nytimes.com/2010/10/31/weekinreview/31bruni.html?\\_r=2&emc=eta1](http://www.nytimes.com/2010/10/31/weekinreview/31bruni.html?_r=2&emc=eta1) (finding Four Loko for sale in New York City at \$3.50 for a 23.5-ounce can); Jenna Johnson & Kevin Sieff, *Four Loko Ban Fuels Buying Binge*, WASH. POST, Nov. 18, 2010, available at <http://www.washingtonpost.com/wp-dyn/content/article/2010/11/18/AR2010111806114.html> (reporting Four Loko sales for as little as \$2 per can).

<sup>82</sup> Some caffeinated malt beverages have an alcohol content as high as twelve percent. See FDA, Consumer Health Information: Serious Concerns Over Alcoholic Beverages with Added Caffeine (Nov. 2010), available at <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM234132.pdf>.

<sup>83</sup> See Fernandes, *supra* note 79, at 1327.

self-consciously aimed at young drinkers.<sup>84</sup> The brand also maintained a broad presence on social media networks,<sup>85</sup> a key strategy in marketing to younger demographics. Four Loko's potent effects and appealing (to some) taste<sup>86</sup> encouraged heavy drinking, which soon earned the drink the appellation "blackout in a can."<sup>87</sup>

Four Loko was not the first alcoholic energy drink,<sup>88</sup> and its popularity spawned a number of imitators.<sup>89</sup> But Four Loko, in particular, nonetheless became the face of a national frenzy over caffeinated alcoholic beverages (CABs) in the fall of 2010. At that time, a rash of articles appeared throughout the country implicating Four Loko in serious incidents of binge drinking

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<sup>84</sup> See Fernandes, *supra* note 79, at 1328; see also Marion Nestle, "Energy" Drinks: Caffeine + Alcohol = Trouble, FOOD POLITICS (Nov. 3, 2010), <http://www.foodpolitics.com/2010/11/energy-drinks-caffeine-alcohol-trouble> (describing how Phusion Products, the producer of Four Loko, was founded by three college friends from Ohio State who designed the drink to capitalize on the popularity among college students of mixing energy drinks and alcohol).

<sup>85</sup> See Abe Sauer, *Four Loko Declines to Own Its Marketing Strategy*, BRANDCHANNEL (Oct. 28, 2010), <http://www.brandchannel.com/home/post/2010/10/28/Four-Loko-Declines-To-Own-Its-Excellent-Marketing-Strategy.aspx> (noting also that Phusion Products attempted to scrub most of its social media presence away after it started receiving negative media attention). Compare Hancock, *supra* note 21, at 280 (stating, in 1979, that "brewers, as well as distillers and vintners, have followed a subdued and conservative course [with regard to advertising] in deference to a critical and sometimes suspicious public"). While Hancock's description now seems quaint, she does appear to have been correct that this approach was the more prudent course toward preventing "further agitation for regulation," *id.*, as the story of Four Loko will demonstrate.

<sup>86</sup> Former *New York Times* food critic Mark Bruni sampled Four Loko and reported that "if you set out to engineer a booze delivery system that is as cloying, deceptive and divorced from the usual smells, tastes and presentation of alcohol as possible, you'd be hard pressed to come up with something more impressive than Four Loko. It's a malt liquor in confectionary drag . . . ." Bruni, *supra* note 81.

<sup>87</sup> See Rebecca Boxhorn, Note, *FDA Goes Loko with Warning Letters*, 12 MINN. J.L. SCI. & TECH. 749, 749-50 & nn.2-3 (2011); Fernandes, *supra* note 79, at 1327 & n.4.

<sup>88</sup> See ALCOHOL JUSTICE, FROM ALCOHOLIC ENERGY DRINKS TO SUPERSIZED ALCOPOPS 2 (2011), available at [http://www.alcoholjustice.org/images/stories/AEDreportFINAL\\_1.pdf](http://www.alcoholjustice.org/images/stories/AEDreportFINAL_1.pdf) (identifying Sparks, a product later purchased by Miller Brewing Company, as the first caffeinated malt beverage to capitalize on the energy-drink-and-alcohol trend).

<sup>89</sup> See Press Release, FDA, Update on Caffeinated Alcoholic Beverages (Nov. 24, 2010), available at <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm234900.htm> (listing five other caffeinated alcoholic beverages, from three other producers, that had drawn FDA attention).



and alcohol poisoning on college campuses.<sup>90</sup> These reports described the problem as resulting in part from the “wide-awake drunk” caused by the combination of caffeine and alcohol, which prevented drinkers from realizing just how much they had consumed.<sup>91</sup> The outcry grew quickly, leading multiple colleges as well as some state governments to ban CABs.<sup>92</sup>

TTB had preapproved the labeling and formulas for these drinks prior to their marketing.<sup>93</sup> Since at least fall 2009, FDA had been aware<sup>94</sup> that multiple state attorneys general had been negotiating for years with major beer manufacturers in an effort to limit the production and sale of CABs.<sup>95</sup> In November 2009, FDA sent letters to CAB producers asking for evidence regarding the safety of adding caffeine to alcoholic beverages.<sup>96</sup> But it was not until the national outcry over Four Loko reached a fever pitch that FDA and TTB (along with the Federal Trade Commission (FTC), which regulates advertising and other business practices alleged to be unfair or deceptive<sup>97</sup>) took affirmative action concerning CABs. On November 17 and 18, 2010, the agencies rolled out a concerted plan.

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<sup>90</sup> See, e.g., Boxhorn, *supra* note 87, at 749 n.2 (collecting articles); Fernandes, *supra* note 79, at 1327-28 nn.2 & 8 (same).

<sup>91</sup> See, e.g., Johnson & Sieff, *supra* note 81.

<sup>92</sup> See *id.*; see also Marion Nestle, *FDA and FTC Get Tough on Caffeine-Alcohol Drinks!*, FOOD POLITICS (Nov. 17, 2010), <http://www.foodpolitics.com/2010/11/fda-to-get-tough-on-caffeine-alcohol-drinks> (reporting that, as of November 2010, five states — California, Michigan, Oklahoma, Utah, and Washington — had banned CABs, and New York’s largest beer distributors had stopped carrying them).

<sup>93</sup> See Nestle, *supra* note 92 (citing statement of Phusion Products).

<sup>94</sup> See ALCOHOL JUSTICE, *supra* note 88, at 5 (reporting that eighteen state attorneys general signed a letter to FDA in September 2009 seeking action against CABs).

<sup>95</sup> See *id.* at 3-4 (describing settlements between state attorneys general and Anheuser-Busch (in June 2008) and MillerCoors (in December 2008) in which the companies agreed to stop producing their CABs).

<sup>96</sup> See Press Release, FDA, FDA To Look Into Safety of Caffeinated Alcoholic Beverages (Nov. 13, 2009), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm190427.htm>.

<sup>97</sup> See *About the Federal Trade Commission*, FED. TRADE COMM’N, <http://www.ftc.gov/ftc/about.shtm> (last visited Apr. 17, 2012).

FDA sent warning letters to four major producers of CABs, including the maker of Four Loko, stating that, as used in their beverages, caffeine constituted an “unsafe food additive,” thus making the products adulterated under the FDCA.<sup>98</sup> FDA explained that the companies’ responses to the November 2009 requests for information had failed to establish that the use of caffeine in these beverages was generally recognized as safe (GRAS) because the data that the companies cited related only to caffeine on its own, not to caffeine and alcohol together.<sup>99</sup> In FDA’s view, the available scientific evidence indicated doubts about the safety of caffeine when used as an additive in alcoholic beverages.<sup>100</sup> Notably, though, FDA’s warning letters addressed not only the physical effects of alcohol mixed with caffeine but also the effects of the drinks’ appearances: the agency stated that one of its concerns in the GRAS analysis was that “these products, presented as fruity soft drinks in colorful single-serving packages, seemingly target the young adult user. Furthermore, the marketing of the caffeinated versions of this class of alcoholic beverage appears to be specifically directed to young adults.”<sup>101</sup> The companies were given fifteen days to correct their violations before FDA would take further action.<sup>102</sup>

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<sup>98</sup> See FDA, Consumer Health Information, *supra* note 82; Warning Letter from Joann M. Givens, Acting Dir., Office of Compliance Ctr. for Food Safety & Applied Nutrition, FDA, to Jaisen Freeman et al., Phusion Projects LLC (Nov. 17, 2010), *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2010/ucm234023.htm>.

<sup>99</sup> See Warning Letter, *supra* note 98.

<sup>100</sup> See *id.* Specifically, FDA relied on studies showing that the mixture of alcohol and caffeine “reduced subjects’ subjective perception of intoxication but did not improve diminished motor coordination or slower visual reaction times” and that it “alter[ed] the perception of alcohol intoxication . . . [such that it] may result in higher amounts of alcohol consumed per drinking occasion, a situation that is particularly dangerous for naïve drinkers.” *Id.* (citing S.E. Ferreira et al., *Effects of Energy Drink Ingestion on Alcohol Intoxication*, 30 ALCOHOL CLIN. EXP. RES. 598-605 (2006); A. Oteri et al., *Intake of Energy Drinks in Association with Alcoholic Beverages in a Cohort of Students of the School of Medicine of the University of Messina*, 31 ALCOHOL CLIN. EXP. RES. 1677-80 (2007)).

<sup>101</sup> *Id.* (citing REDUCING UNDERAGE DRINKING: A COLLECTIVE RESPONSIBILITY (R. Bonnie & M. O’Connell eds., 2004)).

<sup>102</sup> See *id.*

Meanwhile, TTB sent letters to the same four producers, notifying them that because their products were now considered adulterated under the FDCA, those products would also be considered mislabeled under the 1935 Act and thus ineligible for sale or shipment in interstate commerce.<sup>103</sup> FTC also sent letters to all four CAB producers stating that, due to FDA's finding that their products could pose risks to health and safety, any marketing of those products could constitute an unfair or deceptive trade practice.<sup>104</sup>

About a week later, TTB issued an Industry Circular designed to inform other alcoholic beverage producers about the implications of its letters to the four CAB manufacturers.<sup>105</sup> The circular described the scope of the actions taken by TTB and FDA, and it stated that TTB would be consulting with FDA about any future enforcement actions based on the companies' responses to FDA's warning letters.<sup>106</sup> Finally, it reminded producers that getting TTB approval for their beverage formulas is not a guarantee against FDA enforcement for adulteration violations, and that such violations can result in detention of their shipments, suspension of their TTB licenses, and/or fines.<sup>107</sup> FDA also issued an update the day after TTB's circular, announcing that

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<sup>103</sup> See Press Release, TTB, TTB Issues Warnings on the Sale or Shipment of Caffeinated Alcoholic Beverages Determined by FDA to Be Adulterated (Nov. 18, 2010), *available at* <http://www.ttb.gov/press/fy10/press-release-caffeinated-alcohol-beverages1102.pdf>; Letter from Gracie Joy, Ass't Dir., Advertising, Labeling & Formulation Div., TTB, to Jaisen Freeman et al., Phusion Projects LLC (Nov. 18, 2010), *available at* [http://www.ttb.gov/pdf/phusion\\_letter\\_final.pdf](http://www.ttb.gov/pdf/phusion_letter_final.pdf).

<sup>104</sup> See Press Release, FTC, FTC Sends Warning Letters to Marketers of Caffeinated Alcoholic Drinks (Nov. 17, 2010), *available at* <http://www.ftc.gov/opa/2010/11/alcohol.shtm>.

<sup>105</sup> TTB, Industry Circular No. 2010-8 (Nov. 23, 2010), *available at* [http://www.ttb.gov/industry\\_circulars/archives/2010/10-08.html](http://www.ttb.gov/industry_circulars/archives/2010/10-08.html).

<sup>106</sup> See *id.*

<sup>107</sup> See *id.*

three of the four producers had agreed to stop making their CABs and that the fourth — Four Loko’s manufacturer — would begin selling only a non-caffeinated version of its product.<sup>108</sup>

*B. Why FDA and TTB Were Able to Work Together*

In a presentation at the 2010 Symposium on Alcohol Beverage Law & Regulation, an event organized by the National Alcohol Beverage Control Association (an industry trade group), the moderator of a panel on FDA and TTB interaction described the area of CABs as “a regulatory tempest.”<sup>109</sup> Yet just a few months after this presentation took place, FDA and TTB were able to work together to coordinate a response to an acute situation without antagonizing each other over their proper spheres of authority. What factors went into this example of inter-agency cooperation?

First, the presence of added caffeine in alcoholic beverages is a relatively new issue. Although TTB has allowed caffeine in alcoholic beverages for decades — for example, in coffee liqueurs — the use of caffeine as an additive has emerged only in the past decade.<sup>110</sup> As such, TTB did not have a significant history of regulating in this area prior to the emergence of the Four Loko crisis. Of course, TTB was not ignorant of the potential problems with caffeine: in its fiscal year 2009 regulatory agenda, the Department of Treasury had reported that TTB was in the pre-rule stage of “seeking comments on various issues related to the labeling and advertising of alcohol beverages that contain caffeine, vitamins, and minerals.”<sup>111</sup> But the priority was listed as

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<sup>108</sup> See Press Release, FDA, Update on Caffeinated Alcoholic Beverages (Nov. 24, 2010), *available at* <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm234900.htm>.

<sup>109</sup> See Robert C. Lehrman, TTB and FDA: Working Side by Side to Regulate Alcohol Beverages (Mar. 10, 2010), at slide 3, *available at* <http://www.bevlaw.com/files/nabca%20caffeine%20alcohol%20ttb%20fda.pdf>.

<sup>110</sup> See *id.* at slide 11.

<sup>111</sup> See Department of the Treasury, Semiannual Agenda and Fiscal Year 2009 Regulatory Plan (Nov. 24, 2008), at 65, *available at* <http://www.ttb.gov/pdf/treas-fincen-2008-0021-0001.pdf>.

“nonsignificant,”<sup>112</sup> and no notice for comment or proposed rule had emerged from this process before fall 2010.<sup>113</sup> The fact that TTB did not have a system in place on which the agency and the regulated parties had previously relied likely made it possible for TTB to be more flexible in coming to a quick solution with FDA.

Another factor may have been the status of caffeine within FDA’s regulatory agenda for other food products. FDA’s crackdown on the use of caffeine in alcoholic beverages falls outside the agency’s usual treatment of caffeine as a food ingredient or additive. Caffeine in foods and beverages is only lightly regulated as a general matter, and it appears in thousands of products that Americans consume every day.<sup>114</sup> FDA recognizes caffeine as GRAS (up to a certain concentration) when it is added to sodas and other beverages as well as when it occurs naturally in beverages such as coffee and tea.<sup>115</sup> When caffeine is used as an additive, producers must list caffeine as an ingredient, but they do not have to specify the amount or include any warnings.<sup>116</sup> Beverage producers can also avoid even these regulations if they market their products as dietary supplements — an approach used by the manufacturers of many non-alcoholic energy drinks.<sup>117</sup>

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<sup>112</sup> *See id.*

<sup>113</sup> No proposed rule has emerged since the fall 2010 warning letters, either. But this lack of progress may be unsurprising given that TTB has recently chosen to work cooperatively with FDA rather than to strike out on its own.

<sup>114</sup> *See* James G. Hodge, Jr. et al., *The Consumable Vice: Caffeine, Public Health, and the Law*, 27 J. CONTEMP. HEALTH L. & POL’Y 76, 78-79 (2010).

<sup>115</sup> *See id.* at 102-03.

<sup>116</sup> *See id.* at 103. In contrast, products classified as “drugs” under the FDCA must display warning labels if they contain caffeine. *See id.* at 114.

<sup>117</sup> *See id.* at 104. Dietary supplements fall under the purview of the Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 and 42 U.S.C.), which places fewer regulatory burdens on dietary supplements than on items classified as conventional “foods” or as “drugs.” *See* PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW: CASES AND MATERIALS* 261-68 (3d ed. 2007). For instance, an energy drink marketed as a dietary supplement may contain more than twice the amount of caffeine permitted in a soda of the same size that is marketed as a normal beverage. *See* Hodge, *supra* note 114, at 105-06.

Perhaps knowing that caffeine is generally not on FDA's radar made TTB more likely to view the CAB action as an isolated incident that would be unlikely to affect the broader question of control over alcoholic beverage labeling. That is, because the Four Loko controversy involved a substance that (1) appears as an additive in relatively few alcoholic beverages, (2) is not subject to onerous regulatory requirements when added to other foods, and (3) has been approved as GRAS in a number of other uses, TTB might not have seen FDA's involvement in the case as a sign that FDA would be extending its own rules very far into TTB's usual territory. Some industry representatives have worried that FDA and TTB's recent actions could signal a move toward banning all caffeine in alcoholic beverages, which would prove problematic for drinks such as Kahlúa or coffee porter<sup>118</sup> — drinks that have long had TTB approval of their formulas and that are quite unlike the beverages implicated in the Four Loko controversy. But given FDA's usual stance toward caffeine, TTB would be justified in believing that this outcome is unlikely to result from the agencies' cooperation on CABs.

Finally, and most significantly, the agencies' coordinated actions against the CAB producers were able to fit comfortably within the terms of the 1987 MOU.<sup>119</sup> In its newsletter of November 18, 2009 — just after FDA first announced that it would seek information from CAB producers — TTB stated that it was working with FDA on these inquiries, but it also invoked the 1987 MOU, emphasizing that under the MOU “TTB is the agency with a system of specific stat-

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<sup>118</sup> See, e.g., Lehrman, *supra* note 109, at slides 26-27; Press Release, Brewers Ass'n, Brewers Association Calls for Rulemaking on Caffeine-Added Alcohol Beverages (Nov. 16, 2010), *available at* <http://www.brewersassociation.org/pages/media/press-releases/show?title=brewers-association-calls-for-rulemaking-on-caffeine-added-alcohol-beverages> (stating that the Brewers Association, a trade group for small and independent beer producers, would petition TTB to promulgate a rule banning “synthetic and pure caffeine additions” to alcoholic beverages but allowing “incidental caffeine from ingredients that have a long tradition in brewing, such as coffee, chocolate and tea”).

<sup>119</sup> See *supra* note 65 and accompanying text.

utory and regulatory controls over alcohol beverages and . . . FDA has authority regarding determinations of the safety of the food additives used to make alcohol beverages.”<sup>120</sup> TTB also reported in this newsletter that for the past few years it had been communicating with FDA under the MOU’s procedures with regard to the addition of caffeine to alcoholic beverages.<sup>121</sup> The agencies had agreed during that time that caffeine could be added to such beverages at the same level as that allowed for soda products, but pursuant to the requests from the state attorneys general, TTB was expecting FDA to “clarify its position.”<sup>122</sup> That clarity came in the course of the interagency cooperation that produced the FDA and TTB warning letters of November 2010. Because the addition of caffeine to alcoholic beverages could be framed as an “adulteration” issue, the agencies could agree that FDA had jurisdiction to take enforcement action under the FDCA.<sup>123</sup>

In their recent article *Agency Coordination in Shared Regulatory Space*,<sup>124</sup> Jody Freeman and Jim Rossi analyze the role of MOUs in the context of the various coordination tools available to agencies whose regulatory responsibilities overlap. FDA and TTB have a type of “shared regulatory space” that Freeman and Rossi describe as “related jurisdictional assignment[,]” in which “Congress gives each of several agencies authority to regulate a different product or activity, but for the same purpose.”<sup>125</sup> In fact, the authors use the U.S. food system as their main ex-

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<sup>120</sup> TTB, Special Edition Newsletter for Nov. 18, 2009, *available at* [http://www.ttb.gov/newsletters/archives/2009/ttb\\_newsletter111809-special.html](http://www.ttb.gov/newsletters/archives/2009/ttb_newsletter111809-special.html).

<sup>121</sup> *See id.*

<sup>122</sup> *See id.*

<sup>123</sup> *See* 1987 MOU, *supra* note 65, at 45,503 ¶ 2(A).

<sup>124</sup> 125 HARV. L. REV. 1131 (2012).

<sup>125</sup> *Id.* at 1146. Of course, there is some nuance lost in this characterization. As explained above, *supra* note 43 and accompanying text, because TTB’s main responsibility is collecting tax revenue, its regulatory purposes do not always align with FDA’s primary purpose of protecting the public health. However, as far as labeling regulations are concerned, a major part of TTB’s goal is to protect consumers. *See* 27 U.S.C. § 205(e) (authorizing Secretary of the Treasury to

ample of related jurisdictional assignment, since FDA shares responsibility for monitoring Americans' food with at least fifteen other agencies, including the Department of Agriculture, the Environmental Protection Agency, and even the Department of Homeland Security.<sup>126</sup> “Where the extent of fragmentation is severe” in these jurisdictional assignments, Freeman and Rossi note, “related assignments can exacerbate the problem of systemic risk.”<sup>127</sup>

MOUs are the “[p]erhaps the most pervasive instrument of coordination” that agencies use to attempt to overcome the problems and risks of fragmentation.<sup>128</sup> They are particularly useful for agencies to coordinate their internal procedures with regard to an overlapping jurisdictional issue,<sup>129</sup> as the 1987 MOU does with regard to adulteration/mislabeling for additives in alcoholic beverages. The 1987 MOU falls into the category of MOUs designed to “delineat[e] jurisdictional lines” and “establish[] procedures for information sharing,” though agencies may enter into MOUs for any number of other reasons.<sup>130</sup> As a general matter, MOUs have the advantages of “reduc[ing] transaction costs for both [regulated parties] and agencies” and potential-

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promulgate labeling regulations for alcoholic beverages “as will prohibit deception of the consumer with respect to such products” and “as will provide the consumer with adequate information as to the identity and quality of the products”).

<sup>126</sup> Freeman & Rossi, *supra* note 124, at 1147; *see also* Eva Merian Spahn, Note, *Keep Away from Mouth: How the American System of Food Regulation Is Killing Us*, 65 U. MIAMI L. REV. 669, 685-87 (2011) (listing other agencies and their food-related regulatory spheres).

<sup>127</sup> Freeman & Rossi, *supra* note 124, at 1147.

<sup>128</sup> *Id.* at 1161. The authors note that while Congress could, in theory, require agencies to enter into MOUs, and the President could theoretically request them, “there appears to be no generally applicable statutory or executive branch policy regarding the use of MOUs,” so agencies can largely dictate when they enter into such agreements and what their contents will be. *Id.*

<sup>129</sup> *See id.* at 1192.

<sup>130</sup> *Id.* at 1161 (listing other such reasons as including “agreeing to collaborate in a common mission,” “coordinating reviews or approvals where more than one agency has authority to act in a particular substantive area,” and “agreeing on substantive policy,” although the authors note that the latter may require additional steps under the Administrative Procedure Act).



ly “improv[ing] the expertise on which [agencies’] decisions are based.”<sup>131</sup> They can also help agencies “hold each other” to their “concrete commitments,” which makes it more difficult for agencies to shirk their duties and helps offset Congress’s inability to monitor agencies directly.<sup>132</sup> In particular, MOUs can “enabl[e] policy compromises of the sort Congress envisioned when delegating authority to multiple agencies in the first place.”<sup>133</sup> On the other hand, the voluntary nature (and absence of legal enforceability) of MOUs means that some problems might remain unresolved, and the agreements might not remain stable across administrations.<sup>134</sup>

In the case of CABs, the 1987 MOU worked exactly as Freeman and Rossi describe. The agencies made a binding *ex ante* commitment with regard to how they would handle the issue of additives in alcoholic beverages, a question that straddles the line between FDA’s jurisdiction over adulteration and TTB’s jurisdiction over labeling. When an unfamiliar situation arose (due to the recency of caffeine’s appearance in alcoholic beverages), the MOU’s flexibility allowed the agencies to fit the new facts into their established procedures in order to reach a resolution.<sup>135</sup> That resolution took the form of a united stance that gave the CAB producers a single message rather than subjecting them to divergent regulatory requirements, thereby reducing transaction costs. Furthermore, because the question of alcoholic beverage additives could be “divided” in such a way as to keep both agencies involved — with FDA making the “adulteration” determination and TTB making the “mislabeling” determination — the MOU was an appropriate coordina-

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<sup>131</sup> *Id.* at 1164-65. The authors point out that coordination mechanisms such as MOUs can improve decision quality because they “draw on the specialized knowledge of different agencies to produce net gains, rather than . . . combin[ing] the agencies in a way that would destroy their unique capabilities.” *Id.* at 1185.

<sup>132</sup> *See id.* at 1188.

<sup>133</sup> *Id.*

<sup>134</sup> *Id.* at 1165. Interagency coordination mechanisms might also present problems of inappropriate purposes and insufficient transparency. *See id.* at 1189-90.

<sup>135</sup> *See id.* at 1192.

tion mechanism for allowing each agency to rely on its respective rules without appearing to invade the other's territory.<sup>136</sup> While it is difficult to say whether this is exactly the type of compromise that Congress intended when it divided alcoholic beverage jurisdiction between FDA and (the predecessors of) TTB, evidence from the congressional records of 1938 suggests that the legislators who enacted the FDCA would have wanted the agencies to work together on issues regarding the safety of such beverages.<sup>137</sup>

To be sure, the fact that FDA and TTB were able to work together smoothly does not mean that the outcome was ideal. In addition to some producers' discomfort with FDA's new stance toward caffeine in alcoholic beverages,<sup>138</sup> others have objected that the agencies' actions show a preference toward non-alcoholic energy drinks, which are subject to few regulations and which will still be available for consumers to self-mix with alcohol in order to create a drink very similar to the pre-mixed drinks that have been banned.<sup>139</sup> (The market for non-alcoholic energy drinks in the United States is massive: between 2002 and 2007, the market grew by 440 percent, with yearly sales estimated to exceed \$9 billion for 2011.<sup>140</sup>) At least one industry trade group

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<sup>136</sup> Cf. *id.* at 1192-93 ("MOUs are . . . more likely to be implemented[] in situations where the agencies recognize the need for coordination . . . and where conflict among them is not high. Where conflict is high, or where other barriers to coordination are significant, an external prompt, and perhaps centralized supervision, will be necessary.").

<sup>137</sup> See Byszewski, *supra* note 29, at 554-60 (analyzing legislative history and concluding that Congress intended the FDCA's definition of "food" to include alcoholic beverages).

<sup>138</sup> See *supra* note 118 and accompanying text.

<sup>139</sup> See, e.g., *FDA and FTC Banish Four Loko and Joose*, BEVLOG (Nov. 17, 2010), <http://www.bevlaw.com/bevlog/fmb/fda-and-ftc-banish-four-loko-and-joose>.

<sup>140</sup> See Joseph G. Hoflander, Note, *A Red Bull Instead of a Cigarette: Should the FDA Regulate Energy Drinks?*, 45 VAL. U. L. REV. 689, 697-98 (2011). In fact, a major concern about Four Loko and its kindred was that the similar appearance between them and non-alcoholic energy drinks made CABs attractive to underage consumers. See, e.g., Adam Shelton, *The Outlaw Four Loko: FDA Victim or Blackout in a Can?*, THE LEGALITY (Dec. 5, 2010), <http://www.thelegality.com/2010/12/05/the-outlaw-four-loko-fda-victim-or-blackout-in-a-can> (noting this reason as a motivating factor behind Oregon's CAB ban). Young people represent a

publicly opposed FTC’s consent agreement with the producer of Four Loko, arguing that it undermined TTB’s labeling authority<sup>141</sup> and threatened inconsistent and confusing regulations.<sup>142</sup> (However, TTB itself supported the proposed consent decree as consistent with its own labeling regulations, acknowledging that FTC and TTB had consulted on FTC’s proposal.<sup>143</sup>) And some producers have also complained about the “patchwork” of state and federal actions that have emerged in response to the Four Loko incidents.<sup>144</sup> Although FDA and TTB coordinated their responses in the 2010 warning letters, those letters were aimed at specific companies, and the agencies have not undertaken any steps toward a comprehensive national rulemaking with regard to the mixture of caffeine and alcohol.

While these objections from industry may be important to consider in future actions with regard to CABs, they do not change the positive aspects of FDA and TTB’s coordinated response to the CAB problem. The presence of the 1987 MOU was a key part of the agencies’ ability to work together — an important lesson in analyzing the next issue of jurisdictional overlap.

### III. THE PATIENT PROTECTION & AFFORDABLE CARE ACT’S MENU LABELING REQUIREMENTS: JURISDICTIONAL WRANGLING PREVENTS COMPREHENSIVE REFORM

#### *A. The Law and FDA’s Attempts at Implementation*

As compared to some of the other enactments in the Patient Protection & Affordable Care Act<sup>145</sup> (PPACA), the law’s menu labeling requirements have not been in the forefront of the

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major part of the energy drink market. *See* Hodge, *supra* note 114, at 85 (reporting that nearly a third of Americans between the ages of 12 and 24 “regularly” consume energy drinks).

<sup>141</sup> *See* Letter from Joe McClain, Pres., Beer Inst., to Jon Leibowitz, Chairman, FTC (Dec. 2, 2011), at 2-4, *available at* <http://www.ftc.gov/os/comments/phusionprojectsconsent/00257-81843.pdf>.

<sup>142</sup> *Id.* at 6-8.

<sup>143</sup> *See* Letter from John J. Manfreda, Adm’r, TTB, to Donald S. Clark, Comm’r, FTC (Dec. 2, 2011), *available at* <http://www.ftc.gov/os/comments/phusionprojectsconsent/00256-81815.pdf>.

<sup>144</sup> *See, e.g.,* Brewers Ass’n, *supra* note 118 (describing group’s preference for a “clear and consistent national standard”).

<sup>145</sup> Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of the U.S. Code).

news. But in the realm of food law, the PPACA's section 4205<sup>146</sup> represents a major change.<sup>147</sup> That section amends section 403(q)(5)(A) of the FDCA to require the disclosure of "the number of calories contained in [a] standard menu item"<sup>148</sup> for "food . . . that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name . . . and offering for sale substantially the same menu items."<sup>149</sup> As in the models established by state and local regulations that preceded the PPACA, the new law requires this information to appear on menus, menu boards, and drive-through displays.<sup>150</sup> Restaurants must also post "a prominent, clear, and conspicuous statement" making clear that more comprehensive nutrition information is available in writing upon customer request.<sup>151</sup> The restaurants must have a "reasonable basis" for the calorie and nutrient numbers they list.<sup>152</sup> The law instructs the Secretary to promulgate regulations to enforce these requirements within one

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<sup>146</sup> 124 Stat. at 573 (codified at 21 U.S.C. § 343(q)(5)(A)).

<sup>147</sup> See Michelle I. Banker, *I Saw the Sign: The New Federal Menu-Labeling Law and Lessons from Local Experience*, 65 FOOD & DRUG L.J. 901, 904 (2010) (noting that prior to the PPACA's passage, "restaurants were exempt from nutrition labeling requirements mandated by the Nutrition Labeling and Education Act of 1990," Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended at 21 U.S.C. § 343-1)). Legislation similar to the PPACA's section 4205 had been introduced in Congress no less than five times since 2003, but it had failed to advance each time. See *id.* at 904-05. At least one commentator has suggested that the impetus to finally pass section 4205 came from the restaurant industry itself: after twenty-eight states and many major cities passed their own menu labeling laws, the industry had an incentive to seek a consistent federal standard. See Amanda Waldroupe, *Oregon Waits for Menu Labeling to Take Effect*, THE LUND REPORT (July 27, 2011), [http://lundreport.org/resource/oregon\\_waits\\_for\\_menu\\_labeling\\_to\\_take\\_effect](http://lundreport.org/resource/oregon_waits_for_menu_labeling_to_take_effect) (citing statement of the nutrition director of CPSI).

<sup>148</sup> 124 Stat. at 573-74.

<sup>149</sup> 124 Stat. at 573. In addition to posting calorie counts for each item, restaurants must also display "a succinct statement concerning suggested daily caloric intake." 124 Stat. at 574. The provision also covers vending machine operators who have twenty or more vending machines. See 124 Stat. at 575.

<sup>150</sup> See Banker, *supra* note 147, at 903.

<sup>151</sup> 124 Stat. at 574.

<sup>152</sup> *Id.*

year of the PPACA's enactment.<sup>153</sup> Congress also included a revision to the FDCA's food labeling preemption clause providing that the new menu labeling regulations will override any conflicting state laws, but states will still be free to regulate restaurants with fewer than twenty locations.<sup>154</sup>

On July 7, 2010, FDA issued a notice and opportunity to comment on the possibilities for regulation under section 4205.<sup>155</sup> The agency sought information relating to, for instance, current practices in determining and presenting caloric and nutritional information in the restaurant context and current implementation and enforcement mechanisms under state and local laws.<sup>156</sup> Just under two months later, FDA published a draft guidance for the restaurant industry to communicate the agency's "current thinking" on section 4205.<sup>157</sup> To the surprise of many,<sup>158</sup> FDA stated in this guidance that alcoholic beverages would fall under the purview of section 4205 and thus would require calorie listings on restaurant menus.<sup>159</sup> In anticipation of issuing a Notice of Proposed Rulemaking, FDA officially withdrew this guidance on January 25, 2011.<sup>160</sup>

On April 6, 2011, FDA issued the Notice of Proposed Rulemaking for its menu labeling

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<sup>153</sup> *Id.* § 4205(b), 124 Stat. at 575.

<sup>154</sup> *Id.* § 4205(c), 124 Stat. at 576.

<sup>155</sup> Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold From Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010).

<sup>156</sup> *See id.* at 39,027-28.

<sup>157</sup> 75 Fed. Reg. 52,426 (Aug. 25, 2010).

<sup>158</sup> *See, e.g.,* Marion Nestle, *Do You Want Calories Listed for Alcoholic Drinks? Tell FDA by July 5*, FOOD POLITICS (May 24, 2011), <http://www.foodpolitics.com/2011/05/do-you-want-calories-listed-for-alcoholic-drinks-tell-fda-by-june-6> ("The surprise was that FDA had included alcoholic beverages . . .").

<sup>159</sup> *See* FDA, Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010 ¶ III(B)(2) (Aug. 2010) (withdrawn Jan. 2011), *available at* <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodlabelingnutrition/ucm223266.htm>.

<sup>160</sup> *See* Withdrawal of Draft Guidance, 76 Fed. Reg. 4360 (Jan. 25, 2011).

regulations.<sup>161</sup> The proposal was extensive, covering forty-four pages in the Federal Register, but with regard to FDA's alcohol jurisdiction it was notable for just one item: FDA stated that "it is not clear that Congress intended for the nutrition information disclosures required by section 4205 to apply to alcohol beverages, given that the labels of the majority of alcohol beverages are regulated by TTB," and as such, "the new menu labeling requirements do not apply to alcohol beverages."<sup>162</sup> FDA did, however, request comment on this determination.<sup>163</sup> As of the time of this writing, FDA had not yet issued a final rule.

The 2011 proposal's refusal to include alcoholic beverages in the menu labeling requirements met with resistance from consumer groups and other organizations.<sup>164</sup> For instance, one advocacy group has claimed not only that FDA does properly have jurisdiction over menu labeling for alcoholic beverages, but also that it was improper for FDA to defer to TTB, because the latter had failed to take action on its proposed rule regarding alcohol labeling regulations<sup>165</sup> for over four years and did not appear poised to take action soon.<sup>166</sup> Others have suggested that the

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<sup>161</sup> Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192 (Apr. 6, 2011).

<sup>162</sup> *Id.* at 19,203. The rule included no mention of menu labeling for alcoholic drinks over which FDA does have jurisdiction, such as wines and ciders containing less than seven percent alcohol by volume and beers made from grains other than malted barley. *See supra* note 63.

<sup>163</sup> *Id.*

<sup>164</sup> *See, e.g.,* Letter from Gordon F. Tomaselli, Pres., Am. Heart Ass'n, to Div. of Dockets Mgmt., FDA (July 1, 2011), at 4, *available at* [http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm\\_432311.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@adv/documents/downloadable/ucm_432311.pdf); Letter from CPSI et al. to Div. of Dockets Mgmt., FDA (July 5, 2011), at 1, *available at* [http://cspinet.org/new/pdf/ml\\_sign-on\\_letter.pdf](http://cspinet.org/new/pdf/ml_sign-on_letter.pdf); *Tell the FDA to Include Alcoholic Beverages in Restaurant Menu Labeling*, ALCOHOL JUSTICE, <http://alcoholjustice.org/blog/38-blog-entries/629-tell-fda.html> (last visited Apr. 17, 2012).

<sup>165</sup> *See supra* notes 73-78 and accompanying text.

<sup>166</sup> *See Tell the FDA*, *supra* note 164; *cf.* Tim Carman, *MIA: The Empty Calories of Alcohol*, WALL STREET J., Apr. 19, 2011, *available at* [http://www.washingtonpost.com/lifestyle/food/mia-the-empty-calories-of-alcohol/2011/04/13/AFRp0d5D\\_story.html](http://www.washingtonpost.com/lifestyle/food/mia-the-empty-calories-of-alcohol/2011/04/13/AFRp0d5D_story.html) (reporting statement of Wendell Lee, general counsel for the Wine Institute, an industry trade group, opining that FDA declined to include alcoholic beverages because it did not want to get involved in TTB's

TTB jurisdiction issue is just a smokescreen, since FDA’s proposed menu labeling rule includes items such as meat and poultry, which are also regulated by another agency — the USDA.<sup>167</sup> The American Heart Association has argued that this exclusion is contrary to the intent of Congress and potentially detrimental to public health.<sup>168</sup> On the latter point, some commentators have observed that people who order lower-calorie (or what they believe to be lower-calorie) menu items tend to experience a “halo” effect wherein they then order higher-calorie side items such as drinks;<sup>169</sup> if alcoholic beverages are not labeled with their calorie content while food items are, this “halo” effect may persist and cause restaurant patrons to continue to overconsume calorie-dense drinks.<sup>170</sup> Such a result would cut against the congressional intent, in enacting section 4205, to “give consumers important health information, and allow them to exercise choice and responsibility” about what they eat.<sup>171</sup>

There are reasons to be skeptical that the consequences of failing to include alcoholic beverages in FDA’s new regulations will be as serious as some have suggested. While too little

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longstanding attempt to “referee a fight among the wine, beer and spirits industries” over labeling).

<sup>167</sup> See Nestle, *supra* note 158.

<sup>168</sup> See Letter from Gordon F. Tomaselli, *supra* note 164, at 4.

<sup>169</sup> See Banker, *supra* note 147, at 916 (citing P. Chandon & B. Wansink, *The Biasing Health Halos of Fast-Food Restaurant Health Claims: Lower Calorie Estimates and Higher Side-Dish Consumption Intentions*, 34 J. CONSUMER RES. 301, 302 (2007)); cf. Katherine Wilbur, Student Article, *The Informed Consumer Is a Healthy Consumer? The American Obesity Epidemic and the Federal Menu Labeling Law*, 23 LOY. CONSUMER L. REV. 505, 524-25 (2011) (describing how the “halo effect” might cause people to incorrectly assume that menu items without high calorie counts are healthy in general).

<sup>170</sup> See Carman, *supra* note 166 (citing a CPSI spokesperson for the proposition that “a menu where the calories are listed for all of the drinks except for beer, wine and spirits” is “a setup for overindulging on empty calories”). Some chain restaurants’ drinks can have nearly as many calories as an entire meal. For instance, *Wall Street Journal* writer Tim Carman estimates that one cocktail he attempted to order at a Cheesecake Factory restaurant contains somewhere between 590 and 870 calories. *Id.* Unsurprisingly, the Cheesecake Factory (and presumably similar restaurants) currently refuses to disclose to consumers the specific ingredients and the number of calories in their drinks. See *id.*

<sup>171</sup> Banker, *supra* note 147, at 905 (quoting H.R. REP. NO. 111-299 § 2562 (2009)).

time has passed since the first menu labeling laws appeared to be entirely confident in the empirical trends, the early returns on menu labeling have shown mixed results on the extent to which such laws cause consumers to make healthier choices.<sup>172</sup> Following New York City's implementation of a menu labeling ordinance, one study found that seventy-three percent of respondents who viewed the new calorie labels used that information when making their purchasing decisions, while another study found that that number was only fifteen percent.<sup>173</sup> The same variations appear in direct studies of New York consumers' purchasing behaviors.<sup>174</sup> There have been some indications that menu labeling laws incentivize restaurants to make lower-calorie menu options available, but the data in this area is quite incomplete.<sup>175</sup> In sum, then, it is not a sure thing that including calorie counts for alcoholic beverages will in fact cause consumers to change their consumption behaviors.

But these arguments are, to some extent, beside the point. FDA's stated reasoning for its decision to exclude alcoholic beverages from its proposed rule did not rest on the policy arguments for and against the exclusion. Rather, the agency explicitly relied on a legal judgment that FDA did not have the statutory authority to include those beverages within the rule's purview. And this determination highlights the problems of FDA and TTB's longstanding failure to coordinate with regard to ingredient and nutrition labeling for alcoholic beverages.

### *B. The Risks of Failure to Coordinate*

FDA and TTB's inability to come to a resolution regarding ingredient and nutrition labeling for alcoholic beverages has impeded progress in this area for nearly four decades, ever since

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<sup>172</sup> See Banker, *supra* note 147, at 911-15; *Label Nutrition Information at Restaurants*, WHAT WORKS FOR HEALTH, <http://whatworksforhealth.wisc.edu/program.asp?t1=21&t2=12&t3=74&id=265> (last visited Apr. 17, 2012) (collecting studies).

<sup>173</sup> See Banker, *supra* note 147, at 911-12.

<sup>174</sup> *Id.* at 912.

<sup>175</sup> *Id.* at 913-14.



the rulemaking breakdown that led to the *Brown-Forman* decision. FDA has been unable to lend its significant expertise in labeling issues to the question of what should appear on alcoholic beverage labels, and TTB has been unable to promulgate its own rule that would serve as a basis for negotiating with FDA over how FDA should treat alcoholic beverages in the larger context of its food regulations. The arguments over the new menu labeling rule provide a salient example of the problems that this failure to coordinate can cause.

When agencies share regulatory space but fail to implement coordinating mechanisms, they increase the risk of regulatory arbitrage: that is, failure to coordinate can raise “the possibility that regulated entities will seek to take advantage of situations of shared or overlapping authority to get the best deal possible, or play agencies against one another in an effort to drive regulatory standards downward.”<sup>176</sup> Arbitrage is a serious concern in administrative law because it reduces agencies’ accountability and regulations’ effectiveness.<sup>177</sup> The alcoholic beverage labeling area has already experienced exactly this problem, as industry pressure on ATF in the 1970s led to the jurisdictional spat between ATF and FDA that ultimately resulted in the *Brown-Forman* case.<sup>178</sup> Freeman and Rossi observe that “[t]hese kinds of opportunities seem most likely to arise where the delegation scheme allows a single agency to block, dominate, or neutralize others”<sup>179</sup> — just as the *Brown-Forman* court ruled that the 1935 Act allowed ATF to block FDA’s action in an area where the FDCA appeared to allow FDA to regulate.

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<sup>176</sup> Freeman & Rossi, *supra* note 124, at 1185; *see also* Spahn, *supra* note 126, at 686-87 (arguing that federal food regulation is a “haphazard patchwork,” in part because legislation delegating regulatory authority is often passed hastily in response to crises, and as a result “agencies . . . point the finger at each other,” which “results in yet more patchwork legislation and delegation” (citing NEAL D. FORTIN, FOOD REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 28 (2009))).

<sup>177</sup> *See* Freeman & Rossi, *supra* note 124, at 1187.

<sup>178</sup> *See supra* notes 40-48 and accompanying text.

<sup>179</sup> Freeman & Rossi, *supra* note 124, at 1186.

Since *Brown-Forman*, TTB has in fact been subject to industry pressures that have stalled the rulemaking process,<sup>180</sup> and FDA has been unable to counteract this stagnation because *Brown-Forman* barred it from having independent authority in the area of alcoholic beverage labeling. The alcoholic beverage industry's response to FDA's proposed menu labeling regulation provides an instructive example of the potential for arbitrage in this context. In a comment on the 2011 proposed rule, representatives from various beer, wine, and liquor trade groups stated their support for FDA's decision to exclude alcoholic beverages from the rule, arguing that this decision was justified on the basis that TTB had its own rulemaking underway for ingredient and nutrition labeling.<sup>181</sup> Of course, TTB's rulemaking process has been in limbo since 2007 due to conflicts between industry and TTB, which in turn result in part from profit-driven conflicts between industry members themselves.<sup>182</sup> The beverage producers' united position on the menu rule attempts to play FDA and TTB against each other in order to delay the imposition of any regulatory costs.

When situations like these arise, investing in coordination can reduce the risks of regulatory arbitrage by making it harder for the regulated industry to isolate one agency against the other, making it more difficult for agencies to "act unilaterally without consequences," and giv-

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<sup>180</sup> See Carman, *supra* note 166 (noting the competing demands placed on TTB by the wine, beer, and spirit industries with regard to labeling, and citing the view of a wine industry spokesperson that FDA cannot act on the menu labeling question before TTB acts on the labeling question more generally because of the risk of creating two competing regulatory systems).

<sup>181</sup> See Letter from Joseph S. McClain, Beer Inst., et al. to Div. of Dockets Mgmt., FDA (July 5, 2011), *available at* [http://www.brewersassociation.org/attachments/0000/6349/Alcohol\\_Beverage\\_Coalition\\_Comment.pdf](http://www.brewersassociation.org/attachments/0000/6349/Alcohol_Beverage_Coalition_Comment.pdf).

<sup>182</sup> See Carman, *supra* note 166; Lyndsey Layton, *Alcohol Industry Battles Among Itself Over the Issue of Nutrition Labels*, WASH. POST, Dec. 31, 2010, *available at* <http://www.washingtonpost.com/wp-dyn/content/article/2010/12/30/AR2010123004789.html> (describing a "brawl between beer makers and the distilled spirits industry over how to define the average 'serving size' of a drink" and noting the view of one CPSI representative that "the debate over serving size is 'really a stalking horse' for other contentious issues between beer and liquor producers" — specifically, the higher tax rate on distilled spirits than on beer and wine).

ing “stronger” agencies an opportunity to support “weaker” ones in resisting industry pressures.<sup>183</sup> The higher the level of agencies’ commitment to coordination — for instance, by taking part in a joint rulemaking with full APA procedure or by creating a dispute resolution process with a disinterested decisionmaker — the more effective the coordination is likely to be in avoiding arbitrage.<sup>184</sup> The history of relations between FDA and ATF/TTB since the 1970s suggests that the two agencies are not likely to enter into the strongest types of coordination that Freeman and Rossi identify. Further, based on Congress’s repeated failure to legislate with regard to alcoholic beverage labeling authority,<sup>185</sup> there is probably not enough legislative will to force the agencies into a cooperative statutory framework.<sup>186</sup> From the perspective of Freeman and Rossi’s theory, this is unfortunate, because a strong form of coordination such as joint rulemaking can be particularly useful “for harmonizing policies that will be binding on regulated entities, where certainty and consistency are at a premium.”<sup>187</sup>

If the agencies or Congress could muster the necessary political will, a joint rulemaking on alcoholic beverage labeling would in fact be ideal for this regulatory area. FDA would be able to contribute its ingredient and nutritional labeling expertise, while TTB could contribute its expertise on the alcoholic beverage industry generally,<sup>188</sup> thus creating a final rule with better information than either agency would have had on its own. A joint rule would also ensure that

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<sup>183</sup> Freeman & Rossi, *supra* note 124, at 1186.

<sup>184</sup> *See id.* at 1186-87.

<sup>185</sup> *See supra* notes 66-70 and accompanying text.

<sup>186</sup> Compare Freeman & Rossi, *supra* note 124, at 1187 (describing how the Dodd-Frank Act, Pub. L. No. 111-203, 124 Stat. 1379 (2010), created a central decisionmaking authority for coordination among financial regulators).

<sup>187</sup> *Id.* at 1191.

<sup>188</sup> *See id.* at 1172 (observing that joint rulemaking encourages “agencies to pool resources and share expertise”).

the regulated parties would not face the prospect of conflicting obligations.<sup>189</sup> Moreover, a joint rulemaking process would give FDA and TTB a structured setting in which to negotiate the disagreements over alcoholic beverage labeling that have persisted for decades.<sup>190</sup> If the agencies could agree on a general alcoholic beverage labeling regime, then it would be much easier for FDA to determine how such beverages would fit into the larger regime of restaurant menu labeling, since FDA, TTB, and the regulated parties would have baseline expectations and capacities from which to begin negotiating a solution.

As compared to joint rulemaking, MOUs tend to be more useful “for helping agencies to manage internal matters.”<sup>191</sup> This approach would seem to be suboptimal when agencies are trying to determine which regulations will apply to private parties, as FDA and TTB have been doing with regard to alcoholic beverage labeling. Yet in the absence of the willingness or ability to undertake a project as ambitious as a joint rulemaking, a MOU could potentially provide a workable substitute with at least some, if not all, of the advantages of more in-depth coordination mechanisms. As discussed in Part II.B above, the presence of the 1987 MOU helped FDA and TTB to successfully coordinate their responses to the CAB problem even though the MOU did not determine the nature of the substantive rules that would apply to the CAB producers. FDA and TTB could begin the process of reconciling their positions with regard to menu labeling by negotiating a MOU that addresses the presumptive role that TTB labeling regulations — when they finally arrive — will play in FDA’s larger menu labeling regime. This arrangement seems

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<sup>189</sup> See *id.* at 1169-73 (using example of joint rulemaking between the Environmental Protection Agency (EPA) and the National Highway Traffic Safety Administration (NHTSA) to demonstrate how joint rulemaking can minimize inconsistencies and maximize use of agency resources where multiple agencies operate in overlapping jurisdictional arenas).

<sup>190</sup> See *id.* at 1169 (“The agreement [between EPA and NHTSA] to proceed via joint rulemaking provided a forum for resolving a number of potential inconsistencies and conflicts among the federal agencies.”).

<sup>191</sup> *Id.* at 1192.

plausible because it resembles the 1987 MOU's agreement about the role that FDA adulteration determinations will play in TTB mislabeling determinations, an agreement that operated smoothly in the CAB context. And perhaps the process of working together on this MOU would help TTB to clarify some of its positions on calorie and nutrition labeling for alcoholic beverages, a type of insight that the agency could take back to its ongoing negotiations with industry over the final content of the 2007 proposed rule.<sup>192</sup>

### CONCLUSION

Given the lack of congressional action regarding alcoholic beverage jurisdiction in the years since 1935, it appears that some division of authority over alcoholic beverages between FDA and TTB is here to stay, at least for the foreseeable future. However, that does not mean the system cannot be improved from within the current jurisdictional framework. While a system of shared regulatory space might not be ideal in some situations, it can still present opportunities for agency coordination to improve effectiveness and reduce the risks of arbitrage.

The cooperation between FDA and TTB during the CAB crisis demonstrates that the two agencies can work hand-in-hand to address emergent problems in the area of alcoholic beverage regulation when there are clear lines of jurisdictional authority and predetermined processes under which each agency has a defined role. The success of the 1987 MOU in channeling the coordinated CAB response can be a lesson to the agencies when it comes to other issues that cross jurisdictional boundaries.

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<sup>192</sup> See *id.* at 1172 (reporting that EPA and NHTSA's negotiations during the course of their joint rulemaking helped both agencies to "sett[l] important legal questions," "harmoniz[e]" various of their policies, and "require[] staff to broaden their perspectives"); *id.* at 1173 ("[J]oint rulemaking and other similar strategies may be useful even where the goal is not consensus on the substance of the rule.").

One of the reasons why alcoholic beverages' place in the new menu labeling scheme is still indeterminate is that the question falls directly into the interagency void that has existed since *Brown-Forman* stopped FDA from regulating ingredient labeling on alcoholic beverages. In the nearly forty years since that case was decided, FDA and TTB not only have been unable to work together on the substance of alcoholic beverage labeling regulations, but also have been unable to decide on procedures by which the agencies could navigate this thorny jurisdictional issue. As the menu labeling incident demonstrates, even though TTB has a court judgment granting it exclusive jurisdiction over alcoholic beverage labeling, such labeling can still be quite relevant to other FDA regulatory programs. The public and the regulated parties thus would benefit if FDA and TTB managed to coordinate their regulatory schemes. As Freeman and Rossi have suggested for other administrative contexts, joint rulemaking might be the optimal solution to this impasse, since it would allow each agency to contribute its own expertise while reducing the potential for imposing conflicting obligations. But in the absence of the will to undertake such a project, a MOU that addresses how TTB's labeling regulations will fit into FDA's broader regulatory schemes could be a beneficial first step. In any event, it is unlikely that either FDA or TTB will be able to reach its full regulatory effectiveness with regard to alcoholic beverages unless the two agencies find a way to work together.